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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,180	WEI, ZHENG	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54 and 61-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54 and 61-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 25 May 2007 has been entered in full. Claims 55-60 are canceled. New claims 63 and 64 were entered. Claims 1-54, 61-64 are pending and under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 1, 2, 19-21, 28, 29, 46-48 and 54 under 35 U.S.C. 112, second paragraph, as set forth at page 8 of the previous Office Action (20 February 2007), is *withdrawn* in view of the amendment (25 May 2007).

The objection to claims 27, 28 and 54, as set forth at pages 8-9 of the previous Office Action (20 February 2007), is *withdrawn* in view of the amendment (25 May 2007).

Matter of Record

Please note that the objection to claims 27, 28 and 54, as set forth at pages 8-9 of the previous Office Action (20 February 2007), was withdrawn because of the limitations in newly amended claims 27 and 54. These rejections will be reapplied to the instant claims if the claim language is amended. Please see the 35 U.S.C. 112, first paragraph, written description, new matter rejection below.

Claim Rejections-35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-54, 61, 62 (and new claims 63 and 64) remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis for this rejection is set forth at pages 4-8 of the previous Office Action (20 February 2007).

Applicant cites *In re Wands*. Applicant states that the instant invention may require routine experimentation. Applicant recites the instant claims. Applicant argues that ample descriptions of BiRAM and MultiRAM assays are provided in the specification. Applicant cites pages in the specification and Examples 8-10. Applicant maintains that although the identity of the chemoattractant receptor(s) reacting in the assay and causing cell migration is not know immediately following the BiRAM and MultiRAM assays, Applicants teach, for example at page 20, 1st full paragraph, and page 22, lines 1-4 of the instant specification, that RAM assay (i.e. UNiRAM) may be employed for re-screening of the candidate antagonists. Applicant argues that in the RAM assay, only one ligand is applied at a time. Applicant states that additional assay methods, such as conventional HTS methods, such as FLIPR that measure calcium mobilization, or a cell migration assay may be used for discriminating true chemoattractant receptor antagonist hits.

Applicant's arguments have been fully considered but are not deemed persuasive. The specification teaches that in a binary RAM (BiRAM) assay, two types of chemoattractant receptors can be assayed in the same assay. **Either a single cell population comprising two different receptors on one cell or two distinct cell**

populations each comprising a different receptor are incubated with a candidate antagonist(s) and then contacted with an inhibitory concentration of ligands for the target receptor. The ability of the cell populations to migrate in response to the treatment with a candidate antagonist(s) is assayed. If the cell migrates in the presence of a candidate antagonist(s), then a positive signal is observed. As was stated in the previous Office Action, Examples 8-10 (BiRAM assays) are not applicable because the experiments employed known antagonists to known chemoattractant receptors. The instant examples do not teach the incubation of *an unknown candidate antagonist(s)* together with a cell population comprising two different unknown chemoattractant receptors or two distinct cell populations each expressing a different unknown chemoattractant receptor, wherein the unknown candidate antagonist(s) is identified as a true antagonist and its chemoattractant receptor(s) is identified.

Applicant argues that RAM assay may be employed for re-screening of the candidate antagonists and cites page 20, 1st full paragraph, and page 22, lines 1-4 of the instant specification. This argument has been fully considered but not found persuasive. The specification states that although the hits may identify an antagonist to one or more chemokine receptors, the identity of this chemokine receptor(s) reacting in the assay and causing cell migration is not known at this stage of the assay. The specification states that because the hit rate is very low, *i.e.* less than 1%, receptors identity can be then determined by re-screening the candidate antagonist in a RAM assay in which only one chemokine is applied at a time. The specification fails to teach how to use the "hit rate" data from the BiRAM assay and employ it in the RAM assay. It

is unclear how the RAM assay can be used to re-screen candidate antagonists using the results from the BiRAM assay. The RAM assay, as taught in application 10/154,399, was used to identify candidate antagonists (one candidate antagonist at a time) to one known chemokine receptor, using the inhibitory concentrations of one known chemokine ligand. In the BiRAM assay, either a single cell population comprising **two different receptors on one cell** or **two distinct cell populations each comprising a different receptor** are incubated with one or more candidate antagonists and then contacted with an inhibitory concentration of ligands for the target receptor. How does one skilled in the art discern ***which*** chemokine receptor is being affected by the candidate antagonist. If two candidate antagonists are used, how does one skilled in the art discern ***which*** candidate antagonist is affecting ***which*** chemokine receptor. The specification fails to teach how to discern the identity of a particular candidate antagonists or chemokine receptor by re-screening in a RAM assay.

Applicant argues that additional assay methods, such as conventional HTS methods, such as FLIPR that measure calcium mobilization, or a cell migration assay may be used for discriminating true chemoattractant receptor antagonist hits. This argument has been fully considered but is not found persuasive. The instant assays are readouts for activity, but they could not be used to identify *which candidate antagonist* is inducing the cell population migration to the lower chamber if more than one candidate antagonist is placed with the cell population in the upper chamber or *which chemoattractant receptor(s)* is being affected, if a single cell population comprising multiple different chemokine receptors or multiple cell populations comprising different

receptors each are incubated with a candidate antagonist (or candidate antagonists) in the upper chamber.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

NEW OBJECTIONS/REJECTIONS

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claims 27 and 54 initially recited: the method of claim 1 (or the method of claim 28), wherein determining is performed by a method comprising the steps of:

placing a first cell population comprising the first chemoattractant receptor with a candidate antagonist in the upper chamber; placing a second cell population comprising the second chemoattractant with the candidate antagonist in the upper chamber;

placing an inhibitory concentration of a ligand for the first chemoattractant receptor in the lower chamber; placing an inhibitory concentration of a ligand for the second chemoattractant receptor in the lower chamber;

and assaying movement of the first and the second cell population from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of either the first or the second chemoattractant receptor.

The instant claims have now been amended to recite that the first cell population comprising the first chemoattractant receptor with a candidate antagonist is placed in the upper chamber, the inhibitory concentration of a ligand for the first chemoattractant receptor is placed in the lower chamber and the movement of the first cell population from the upper chamber to the lower chamber is assayed, wherein movement identifies the candidate antagonist as an antagonist of the first chemoattractant receptor, ***THEN*** the second cell population comprising the second chemoattractant receptor with the candidate antagonist is placed in the upper chamber, the inhibitory concentration of a ligand for the second chemoattractant receptor in the lower chamber and the movement of the second cell population from the upper chamber to the lower chamber is assayed, wherein movement identifies the candidate antagonist as an antagonist of the second chemoattractant receptor..

The specification as originally filed does not provide support for the invention as now claimed. Applicant's amendment, filed 25 May 2007, asserts that no new matter has been added and contends that claims 27 and 54 were amended to relate to form and/or grammar for the purpose of increasing the clarity of each. Applicant does not

provide sufficient direction for the written description for the above-mentioned "limitations" and the Examiner cannot locate the wording or connotation of the instant claims.

Applicant's arguments regarding the amendments to claims 27 and 54 are not found persuasive. The newly amended claims clearly change the order of the method steps and now recite limitations, which were not disclosed previously. The instant claims recite limitations that were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to **provide specific written support** for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections-35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is indefinite because the method is drawn to two different cell populations: each cell population comprising a chemoattractant receptor, a candidate antagonist and an inhibitory concentration of a ligand. However, claim 27 depends from

claim 1, which recites **a single population expressing two different chemoattractant receptors.** Claim 27 is indefinite because it is unclear **which** first chemoattractant receptor from claim 1 is being examined in claim 27 (i.e. the first or the second chemoattractant receptor in the single population).

Claims 63 and 64 contain the trademark/trade name FLIPR™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the assay and, accordingly, the identification/description is indefinite.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
8/3/07

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